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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,086	03/11/2007	Timothy Kirk Gallaher	89188.0115	5128
26021 7590 09/19/2007 HOGAN & HARTSON L.L.P. 1999 AVENUE OF THE STARS SUITE 1400 LOS ANGELES, CA 90067				
			EXAMINER LOCKARD, JON MCCLELLAND	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 09/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,086	<b>Applicant(s)</b> GALLAHER ET AL.	
	<b>Examiner</b> Jon M. Lockard	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 25-44 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Alignment</u> .               |

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 25, 27, 29-30, 32-34, 37-38, and 41-42 (each in part), in so far as they are drawn to hHSS1 polypeptides of SEQ ID NOs:1 and 21, encoded by the nucleic acid of SEQ ID NO:5.

Group II, claim(s) 25, 27, 29-30, 32-34, 37-38, and 41-42 (each in part), in so far as they are drawn to hHSM1 polypeptides of SEQ ID NOs:3 and 23, encoded by the nucleic acid of SEQ ID NO:7.

Group III, claim(s) 25, 27, 29-30, 32-34, 37-38, and 41-42 (each in part), in so far as they are drawn to hHSC1 polypeptides of SEQ ID NOs:9 and 25, encoded by the nucleic acid of SEQ ID NO:11.

Group IV, claim(s) 25, 27, 29-30, 32-34, 37-38, and 41-42 (each in part), in so far as they are drawn to hHSC2 polypeptides of SEQ ID NOs:13 and 27, encoded by the nucleic acid of SEQ ID NO:15.

Group V, claim(s) 25, 27, 29-30, 32-34, 37-38, and 41-42 (each in part), in so far as they are drawn to hHSC3 polypeptides of SEQ ID NOs:17 and 29, encoded by the nucleic acid of SEQ ID NO:19.

Group VI, claim(s) 26, 28, 31, 35-36, 39-40, and 43-44 (each in part), in so far as they are drawn to mHSS1 polypeptides of SEQ ID NOs:2 and 22, encoded by the nucleic acid of SEQ ID NO:6.

Group VII, claim(s) 26, 28, 31, 35-36, 39-40, and 43-44 (each in part), in so far as they are drawn to mHSM1 polypeptides of SEQ ID NOs:4 and 24, encoded by the nucleic acid of SEQ ID NO:8.

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Group VIII, claim(s) 26, 28, 31, 35-36, 39-40, and 43-44 (each in part), in so far as they are drawn to mHSC1 polypeptides of SEQ ID NOs:10 and 26, encoded by the nucleic acid of SEQ ID NO:12.

Group IX, claim(s) 26, 28, 31, 35-36, 39-40, and 43-44 (each in part), in so far as they are drawn to mHSC2 polypeptides of SEQ ID NOs:14 and 28, encoded by the nucleic acid of SEQ ID NO:16.

Group X, claim(s) 26, 28, 31, 35-36, 39-40, and 43-44 (each in part), in so far as they are drawn to mHSC3 polypeptides of SEQ ID NOs:18 and 30, encoded by the nucleic acid of SEQ ID NO:20.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is directed to a polypeptide comprising the sequence of SEQ ID NO:1 or a variant polypeptide corresponding to SEQ ID NO:1 in which one or more amino acids are replaced, deleted, inserted, and/or added. However, since Baker et al. (US 2003/0073129 A1, filed 04 September 2001) teach a polypeptide set forth as SEQ ID NO:372 that shares 90% sequence identity to SEQ ID NO:1 of the Instant Application (See attached sequence alignment), no special technical feature exists for group I as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Because the technical feature of Group I is not a special technical feature, and because the technical features of the Groups II-X inventions is not present in the Group I claims, unity of invention is lacking. Furthermore, the polypeptides of Groups I-X are structurally and functionally different chemical compounds, having different amino acid sequences, structures and activities, and each of which can be made and used without the other compounds. Lack of unity is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

3. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

4. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be

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considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

5. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

6. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 7:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Manjunath N. Rao**, can be reached on **(571) 272-0939**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).



Jon M. Lockard, Ph.D.  
September 11, 2007